where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users. (2) In that representations in the labeling that it would be efficacious in the treatment of asthma, including the relief of paroxysms or spasmodic attacks, bronchial trouble including bronchitis and bronchial colds, and hay fever, and that it would preserve health, were false and misleading since it would not be efficacious for such purposes.

On June 30, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS SEIZED BECAUSE OF FAILURE TO COMPLY WITH OFFICIAL OR OWN STANDARDS OR BECAUSE OF SUBSTITUTION[2]

461. Adulteration and misbranding of ampuls of ephedrine sulfate, quinine dihydrochloride, and pituitary solution. U. S. v. American Parentrasol Laboratories, Inc., and George Blank. Corporation fined $400; George Blank fined $400. (F. D. C. No. 2898. Sample Nos. 54573–D, 55419–D, 55461–D, 14938–E.)

These products were all drugs recognized in the National Formulary and their strength or quality differed from that set forth in that compendium. The ampuls of quinine dihydrochloride also fell below the standard declared on their labels.

On February 13, 1941, the United States attorney for the District of Connecticut filed an information against American Parentrasol Laboratories, Inc., Bridgeport, Conn., and George Blank, alleging shipment within the period from on or about July 12, 1939, to on or about May 24, 1940, from the State of Connecticut into the States of Michigan and Pennsylvania of quantities of the above-named drugs which were adulterated and misbranded.

The ephedrine sulfate was alleged to be adulterated in that it purported to be or was represented as ampuls of ephedrine sulfate, a drug the name of which is recognized in the National Formulary, and its strength differed from or its quality fell below the standard set forth in that compendium since it yielded an amount of ephedrine corresponding to less than 72.6 percent, namely, not more than 58.4 percent of the labeled amount of ephedrine sulfate; whereas the National Formulary provides that ampuls of ephedrine sulfate shall yield an amount of ephedrine corresponding to not less than 72.6 percent of the labeled amount of ephedrine sulfate. It was alleged to be misbranded in that the statements, (ampul) "1 c.c.—¾ gr. Ephedrine" and (box) "1 c.c.—¾ gr. Ephedrine Sulphate," were false and misleading, since each cubic centimeter of the article did not contain ¾ grain but did contain a smaller amount, namely, slightly more than ⅔ grain of ephedrine, and each cubic centimeter did not contain ¾ grain of ephedrine sulfate but did contain a smaller amount, namely, approximately 0.6 grain of ephedrine sulfate.

The quinine dihydrochloride was alleged to be adulterated in that it purported to be or was represented as ampuls of quinine dihydrochloride, a drug the name of which is recognized in the National Formulary, and its strength differed from or its quality fell below the standard set forth in that compendium in that it yielded less than 95 percent, namely, approximately 55.3 percent of the labeled amount of quinine dihydrochloride; whereas the National Formulary provides that ampuls of quinine dihydrochloride shall yield not less than 95 percent of the labeled amount of quinine dihydrochloride, and its difference in strength or quality from such standard was not plainly stated on its label. It was alleged to be misbranded in that the statements, (ampul) "1 c. c. Quinine Dihydrochloride 7½ grs." and (box) "1 c. c. Quinine Di HCL * * * 7½ grs.," were false and misleading, since each cubic centimeter of the article contained less than 7½ grains, namely, 4.15 grains of quinine dihydrochloride.

The pituitary solution was alleged to be adulterated in that it purported to be or was represented as ampuls of posterior pituitary, a drug the name of which is recognized in the National Formulary, and its strength differed from or its quality fell below the standard set forth in that compendium, since 1 cubic centimeter produced an activity upon the isolated uterus of a virgin guinea pig corresponding to less than 80 percent, namely, not more than 62½ percent of that produced by 0.005 gram of the standard powdered posterior pituitary; whereas the National Formulary provides that unless otherwise stated on the label, ampuls of posterior pituitary contain measured quantities of sterile

[2] See also Nos. 426, 429, 436, 446, 449, 458.

liquor pituitarii posterii, a drug recognized in the United States Pharmacopoeia, which provides that 1 cubic centimeter of solution of posterior pituitary shall produce an activity upon the isolated uterus of a virgin guinea pig corresponding to not less than 80 percent of that produced by 0.005 gram of the standard powdered posterior pituitary.

The information also charged the shipment in interstate commerce in violation of the Food and Drugs Act of 1906 of a quantity of Ovestrin in Oil which was adulterated and misbranded, as reported in N. J. No. 31136 published under that act.

On May 6, 1941, pleas of nolo contendere having been entered on behalf of the defendants, the court imposed a fine of $400 on the corporation and $400 on George Blank. (Both defendants were fined $100 on the counts charging violation of the Food and Drugs Act, but imposition of the sentence was suspended with respect to George Blank on these counts and he was placed on probation for a period of 2 years.)

462. Adulteration and misbranding of ammoniated mercury ointment, phenobarbital and atropine sulfate tablets, and Vitaphosphates. U. S. v. Physicians Drug & Supply Co. Plea of nolo contendere. Fine, $500. (F. D. C. No. 2843. Sample Nos. 14174-E, 14476-E, 14477-E, 14492-E.)

The ammoniated mercury ointment contained a smaller proportion of mercury than that required by the standard set forth in the United States Pharmacopoeia and of that declared on its label; the phenobarbital and atropine sulfate tablets contained no phenobarbital and no atropine sulfate, but did contain 1/33 grain of strychnine sulfate; and the Vitaphosphates contained approximately only one-eighth the amount of vitamin B_1 declared on the label.

On December 4, 1940, the United States attorney for the Eastern District of Pennsylvania filed an information against Physicians Drug & Supply Co., a corporation at Philadelphia, Pa., alleging shipment on or about April 16 and 30, 1940, from the State of Pennsylvania into the State of New Jersey, of quantities of the above-named drugs that were adulterated and misbranded.

The ammoniated mercury ointment was alleged to be adulterated in that it purported to be a drug the name of which is recognized in the United States Pharmacopoeia, 11th Revision, but its strength differed from the standard set forth in such compendium in that it contained ammoniated mercury corresponding to not more than 3.22 percent of mercury; whereas the pharmacopoeia provides that ammoniated mercury ointment shall contain ammoniated mercury corresponding to not less than 7.1 percent of mercury, and the respect in which its strength differed from such standard was not stated plainly on the label. It was alleged to be misbranded in that the statement "Ammoniated Mercury Ointment Five (5%) Per Cent," borne on the jar label, was false and misleading since it did not contain 5 percent of ammoniated mercury but did contain a smaller amount, namely, not more than 4.1 percent of ammoniated mercury.

The phenobarbital and atropine sulfate tablets were alleged to be adulterated in that their strength differed from and their purity or quality fell below that which they purported or were represented to possess, since each of said tablets was represented to contain 1/4 grain of phenobarbital and 1/300 grain of atropine sulfate, whereas they contained no phenobarbital and no atropine sulfate but did contain approximately 1/33 grain of strychnine sulfate. They were alleged to be adulterated further in that tablets each containing approximately 1/33 grain of strychnine sulfate had been substituted in whole or in part for tablets each containing 1/4 grain of phenobarbital and 1/300 grain of atropine sulfate, which they purported to be. They were alleged to be misbranded in that the statement, "Each Tablet Contains: Phenobarbital Gr. 1/4 * * * Atropine Sulphate Gr. 1/300," borne on the bottle label, was false and misleading since the said tablets contained no phenobarbital and no atropine sulfate but did contain approximately 1/33 grain of strychnine sulfate. They were alleged to be misbranded further in that tablets each containing approximately 1/33 grain of strychnine sulfate had been offered for sale under the name of another drug.

The drug Vitaphosphates was alleged to be adulterated in that its strength differed from or its quality or purity fell below that which it purported or was represented to possess, in that each fluid ounce was represented to contain 400 U. S. P. units of vitamin B_1; whereas each fluid ounce contained less than 400 U. S. P. units, namely, not more than 50 U. S. P. units, of vitamin B_1. It was alleged to be misbranded in that the statement "Each Fluid Ounce Contains: Vitamin B_1 400 units," borne on the bottle label, was false and misleading